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(12) # EUROPEAN PATENT SPECIFICATION

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(54) **A heart valve prosthesis.**

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GB-A-1 598 112
US-A-3 574 865
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Description

This invention relates to a heart valve prosthesis. Heart valve prostheses have previously been proposed in a number of forms. An early development in prosthetic heart valves involved the use of various types of mechanical valves such as flap valves or poppet valves. However, heart valve prostheses have utilised three flexible cusps. The cusps are in the form of flexible leaflets which are mounted for flexing about a generally cylindrical base. The leaflets can flex inwardly from the base into a closed position and can flex outwardly to lie in a general cylindrical formation in an open position. Two different types of tissue leaflet valves are commonly manufactured. In one type, complete porcine aortic valves are mounted inside a cylindrical support frame, commonly referred to as a stent. In another type, the leaflets are manufactured from bovine pericardium and also mounted on a frame. Normally the leaflets are mounted on their frame after having been treated with glutaraldehyde which crosslinks and stabilises the collagen in the leaflets and reduces their antigenicity. Materials other than porcine aortic valves or bovine pericardium have been proposed for valve leaflets, for example polyurethane,but valves incorporating leaflets of such other materials are not commercially available for clinical implant at present.

Various forms of frames have been proposed for the foregoing purpose. In, for example, British patent No. 1,598,112, there is disclosed a heart valve prosthesis wherein the frame is formed by a frame system having a first frame defining three parallel legs on which the leaflets are mounted. A second frame cooperates with the first frame in order to clamp the leaflets therebetween so that the leaflets can be secured to and between the frames.

In European Patent Publication No. 0051451A a heart valve prosthesis is shown in which a frame having a cylindrical base from which extends three integral upstanding legs is formed of a biologically compatible metal or plastic material. Three cooperating valve leaflets are mounted on the frame and are secured to the cylindrical base and to the upstanding legs by stitching. Stitches, referred to as coaptation stitches, secure each leaflet to the upper end of each leg in order to try to ensure that the leaflets deflect inwardly to enable the three leaflets to cooperate together to close the passage through the valve. The frame is covered with a cloth in order to achieve well known biological advantages. The cloth also facilitates the fixing of an annular sewing ring to the outside of the prosthesis.

The above-described previously proposed arrangements have been found to be satisfactory in operation but because of their relatively complex construction and assembly, which inv lves sewing or the like in order t secure the leaflets t the frame, th y have disadvantages in that they do not r adily lend themselves t mass production t chniques and are consequently r latively expensive to produce. The durability of these valves is not ideal. Mechanical failures and tears in the leaflets have been reported in the short term and biological effects such as calcification can cause valve malfunction in the longer term.

US Patent No 4,470,157 discloses a heart valve prosthesis in which heart valve leaflets, formed in one or more tissue sections, are located between a pair of scalloped stents. The arrangements described however, for locating the leaflets between the stents have a disadvantage in that the leaflets cannot easily be precisely located in relation to the stents during assembly or subsequent interchanging of the leaflets.

An object of the present invention is to provide a stent for a heart valve prosthesis in which some of the foregoing disadvantages are obviated or mitigated.

According to the present invention there is provided a heart valve prosthesis comprising an annular support frame member for a plurality of flexible tissue valve elements, said support frame member having a plurality of spaced posts defining openings therebetween to permit a portion of each valve element to flex from an open position to a closed position, means for securing the valve elements to the support frame member comprising an annular sleeve member concentric with said support frame member adapted to clamp a nonflexing portion of each valve element in operative position between the support frame and said sleeve, one of said sleeve member and said frame member having a plurality of projections extending from said one towards said other member and said members being adapted to be secured to each other characterised in that the projections are pins which serve to secure the sleeve and frame members together and to effect operative location of each element by extending therethrough for engagement with holes in the other of said members.

Preferably, the pins are provided on the annular support frame member and the valve elements and sleeve member are mounted on the pins to clamp the valve elements in their operative position.

Preferably also, the profile of the clamping sleeve substantially corresponds to the profile of the annular support.

An embodiment of the present invention will now be described by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a heart valve prosthesis in accordance with the present invention incorporating an inner frame and an outer support sleeve securing a valve tissue provided by three valve leaflets therebetween. The prosthesis is provided with an outer cloth covering and an annular sewing ring;

Fig. 2 is a perspective view of th inner frame;

Fig. 3 is a perspective vi w of the uter supp rt sleeve;

Figs. 4a and 4b are diagrammatic representations illustrating vertical and h rizontal secti ns f a valve leaflet; and

Fig. 5 is a fragmentary vertical sectional view, to an enlarged scale, of a portion of the prosthesis illustrating the manner in which each valve leaflet is supported between the frame and the outer support sleeve.

The prosthetic valve is intended for the atrio-ventricular or ventricular-aortic positions within a human heart and can have a range of sizes of from 25 to 33 mm. diameter for the mitral position and 19 to 27 mm. diameter for the aortic position. The prosthesis as illustrated in the accompanying drawings comprises an inner frame 11 of any suitable biologically inert metal or synthetic plastics material, e.g., acetal. The frame 11 comprises a cylindrical base 12 from which extend upwardly towards the outflow end of the valve three spaced posts 13 integral with the base 12 and which posts define scalloped spaces or sectors 14 therebetween. The outer peripheral edges of the base 12 and posts 13 defining the scallops 14 are bevelled. Mounted in the frame 11 so as to project radially outwardly from the cylindrical base 12 are a plurality of e.g., seven tissue-locating pins or similar projections 15. It will be appreciated that the pins 15 do not project radially inwardly beyond the inner surface of the frame 11. From each post 13, a pair of studs 16 extend radially outwardly therefrom and washer elements (not shown) are engaged with said studs in order to secure a tissue therebetween.

A tissue formed of bovine pericardium or any other suitable natural or synthetic material is utilised to form three valve leaflets 17. The three leaflets 17 are secured to the inner frame 11 by affixing the leaflets 17 on to the seven outwardly projecting pins 15 and two studs 16. The perimeter of each scallop 14 is defined by the intersection of a sphere of approximately 11 mm. radius with the cylindrical base 12 of frame 11. As indicated in Fig. 2, the width W of the tip of the posts 13 is approximately 2 mm., the scallop depth *h* is 14 mm. and the overall height H of the frame is 18 mm. The internal diameter of the frame 11 is approximately 23 mm. and its outside diameter approximately 25 mm.

An outer support sleeve 18, which is of a suitable flexible biologically inactive material, e.g., acetal, is adapted to be positioned over the external surface of the adjoining leaflets and secured over the outer ends of the pins 15 in order to clamp the lower portion of the leaflets 17 between the inner frame 11 and the outer sleeve 18. Once again, it will be appreciated that the pins 15 do not extend beyond the outer surface of the outer sleeve 18. The outer sleeve 18 has a cylindrical base 19 provided with a series of holes 19a adapted to register with the pins 15 of frame 11. The sleeve 18 also has spaced upstanding posts 20 similar to corresponding portions of the inner frame 11 so that the profiles of the frame 11 and uter sleeve 18 are generally in register with each other when they are located in their operative positions relative to one other. The outer sleeve 18, however, is provided with posts 20 which are broad r than thos of the inner frame 11 in a circumferential direction and each has a vertical slot 21 adjacent the overlapping region and into which slots the studs 16 and their associated securing washers project. The cylindrical base 19 of the outer sleeve 18 is also provided with vertical slits 22 at the location of each post to enable the cylindrical base 19 of the outer sleeve 18 to be sufficiently distorted to allow it to be easily clipped in position around the base 12 of the inner frame 11 to which the leaflets 17 have been affixed.

The base of the scallop of the outer frame 18 projects 1 mm. above the base 12 of inner frame 11 and the top of the posts 20 project about 2 mm. above their associated posts 13 of the frame 11. As indicated in Fig. 3, the overall height H' of outer sleeve 18 is 20 mm. and the scallop depth h' is 15 mm. The outside diameter of the outer sleeve 18 is 27 mm. and the internal diameter is about 26 mm. The width W' of each post 20 at its upper tip is 7 mm. and the vertical slots 21 are approximately 2 mm. wide.

As shown in Fig. 4a in vertical section, one suitable form of each leaflet 17 at its flexible portion above the base 12 of frame 11 defines an initial angle of about 20° before curving through a radius R of about 11 mm. to extend towards its free edge in a substantially vertical direction. The height h'' of the leaflet is approximately 15 mm. Fig. 4b shows the arcuate form of each leaflet when operatively located between its associated posts 13. Each leaflet 17 is preferably manufactured from bovine pericardium selected from specific areas of pericardial sac to give uniform thickness and extensibility. In manufacture of each leaflet it is positioned in a mould and placed in a glutaraldehyde bath to crosslink the tissue and produce the desired geometry for the leaflets. Holes for positioning each leaflet 17 on the pins 15 and studs 16 of the frame 11 are also made when each leaflet is on the mould.

It will be noted that the tips of the posts of the outer sleeve 18 are rounded in order to reduce the risk of myocardial injury in the atrio-ventricular position.

Fig. 5 illustrates, to an enlarged scale, the manner in which, in practice, the sleeve 18 and frame 11 engage and support a valve leaflet 17. Prior to assembly, the frame 11 is enclosed in a covering 24 formed from a single piece of pericardial tissue. The tissue covering 24 is stitched at 25 to provide a double-layer tail 26 of tissue extending therefrom. It will be noted that the inner face of the frame 11 is seamless. The sleeve 18 is covered with a covering 27 of a cloth such as polyester which is stitched at 28 to provide a double-layered extension in the form of a cloth tail 29.

On assembly of the prosthesis of the invention, valve leaflets 17 are positioned on the outwardly extending pins 15 and studs 16 f the tissue-covered inner frame 11 the leaflets being secured to each other by vertical stitched seams at their adjacent edges and tips. Securing washers (n t sh wn) are then releasably affixed t th studs 16

to secure the leaflets 17 thereto. The cloth-covered outer sleeve 18 is then positioned, as shown in Fig. 5, on the outside of the mounted leaflets 17 on the pins 15 and base 19 of the outer sleeve 18 is secured on to the inner frame 11 by means of a surrounding acetal locking or clamping ring 30, the vertical edges of leaflets 17, the studs 16 and associated securing washers being accommodated within the slots 21 (Fig. 3) of the outer sleeve 18. In this way, each valve leaflet 17 can be mounted accurately and securely in their desired position without the necessity for highly skilled suturing. The clamping of the tissue between the cloth-covered sleeve 18 and tissue covered frame 11 provides an even distribution of pressure on each valve leaflet 17 at its base regions and the studs 16 towards the top of the posts 13 will precisely locate the leaflets 17 thereon. In addition, the outer sleeve 18 protects the pericardial tissue against injury during insertion of the prosthesis and also against possible injury from long suture ends in the aortic position.

As shown in Fig. 5, an external double-layer cloth panel 31 is secured by stitching at 32 to the tissue tail 26.

The cloth tail 29 of the cloth covering 27 of the outer sleeve 18 is folded upwardly over the outer face of locking ring 30 and the inner layer of tail 29 is secured by stitching at 33 along the upper edge of said ring. The tissue tail 26 and cloth panel 31 are subsequently folded upwardly over the secured tail 29 stitched at 33a. The outer layer of the cloth panel 31 is stitched at 34 to the inner layer of tail 29. The tissue tail 26 extends outwardly around the base of the valve to prevent host tissue ingrowth into the valve orifice. The outer layer of panel 31 and inner layer of tail 29 are continued upwardly and wound in a spiral and stitched at 35 to outer layer of panel 31 to form a sewing ring 36 whereby the prosthesis can be secured in its operative position. It will be apparent that the position of the sewing ring relative to the prosthesis can be varied as required in order to give a higher or lower valve profile as required.

If desired, in the atrio-ventricular position the posts 20 of the outer sleeve 18 can be linked by a connecting suture 23 (Fig. 1) to reduce the chance of snaring of sutures on the posts during insertion.

The prosthesis described above is intended for a 27 mm. atrio-ventricular valve and it will be appreciated that the dimensions can be varied in order to suit requirements and for other valves which have to be employed at other locations.

Although it has commonly been found desirable to provide three valve leaflets in a heart valve prosthesis of the type to which the present invention relates, it will be appreciated that it may be possible to use a number of leaflets other than three e.g., two.

It will be appreciated by those skilled in the art that the beneficial functions of a valve produced in accordance with the present invention depend upon care being taken with respect to a number of parameters, e.g., selection and preliminary treatment of the valve leaflets in accordance with accepted practice.

Claims

1. A heart valve prosthesis comprising an annular support frame member (11) for a plurality of flexible tissue valve elements (17), said support frame member (11) having a plurality of spaced posts (13) defining openings therebetween to permit a portion of each valve element (17) to flex from an open position to a closed position, means for securing the valve elements to the support frame member comprising an annular sleeve member (18) concentric with said support frame member (11) adapted to clamp a non-flexing portion of each valve element (17) in operative position between the support frame (11) and said sleeve (18), one of said sleeve member (18) and said frame member (11) having a plurality of projections (15) extending from said one towards said other member and said members being adapted to be secured to each other characterised in that the projections (15) are pins which serve to secure the sleeve and frame members together and to effect operative location of each element (17) by extending therethrough for engagement with holes in the other of said members.

2. A prosthesis as claimed in claim 1, in which the pins (15) are formed on the support frame member (11) and extend outwardly therefrom to engage holes (19a) in the surrounding sleeve member (18).

3. A prosthesis as claimed in any of claims 1 or 2, in which the sleeve member (18) is provided with a plurality of integral extensions (20), each of which is adapted to overlie one of the posts (13) of the support frame member (11).

4. A prosthesis as claimed in claim 3, in which each frame post (13) is provided with a projecting stud or studs (16) on which the valve elements (17) are mounted.

5. A prosthesis as claimed in claim 4, in which each projecting stud (16) is formed on the support frame post (13) and is provided with means for securing a valve element or elements (17) thereto.

6. A prosthesis as claimed in claim 5 in which the securing means is a washer or the like adapted to be releasably clipped on to its associated stud (16).

7. A prosthesis as claimed in any of claims 3 to 6, in which each sleeve extension (20) has formed therein a slot (21) adapted to receive means for joining adjacent tissue leaflets (17).

8. A prosthesis as claimed in any preceding claim in which the sleeve member (18) is provided with a plurality of slits (22) spaced circumferentially from each other and each extending partially along the length of the sleeve member (18), said slits (22) permitting deformation of the sleeve member (18) in order to enable releasable interengagement of the sleeve member (18) about the support frame member (11).

9. A prosthesis as claimed in any preceding

claim, in which an annular locking ring (30) is provided for location about the external surface of the sleeve in order to retain the sleeve member (18) in engagement with the support frame member (11).

10. A prosthesis as claimed in any preceding claim, in which the support frame member (11) is entirely surrounded by a covering (24) of tissue whereby the inner face of the covered support frame member (11) is seamless.

11. A prosthesis as claimed in claim 10, in which the base (12) of the frame member (11) and the sleeve member (18) is covered with a continuous piece of tissue.

12. A prosthesis as claimed in any preceding claim, in which the sleeve member (18) is entirely surrounded by a covering (27) of cloth.

13. A prosthesis as claimed in claim 12, in which the cloth covering (27) has an extension formed into a sewing ring (36) extending around the outer circumference of the prosthesis.

14. A prosthesis as claimed in claim 4, in which the integral extensions (20) of the sleeve member (18) are linked by a connecting suture (23) to reduce the possibility of snaring during insertion of the prosthesis.

Patentansprüche

1. Herzklappenprothese mit einem ringförmigen Tragrahmenteil (11) für eine Anzahl von biegsamen Gewebeklappenelementen (17), welches eine Anzahl beabstandeter Stützen (13) aufweist, die Öffnungen zwischen sich begrenzen, um einem Abschnitt jedes Klappenelementes (17) zu erlauben, sich von einer offenen Stellung in eine geschlossene Stellung durchzubiegen und mit Mitteln zum Befestigen der Klappenelemente an dem Tragrahmenteil, die ein mit dem Tragrahmenteil (11) konzentrisches ringförmiges Hülsenteil (18) aufweisten, das zum Einklemmen eines sich nicht durchbiegenden Abschnittes jedes Klappenelementes (17) in Einsatzstellung zwischen dem Tragrahmenteil (11) und der Hülse (18) vorgesehen ist, wobei entweder das Hülsenteil (18) oder das Rahmenteil (11) mit einer Anzahl von Vorsprüngen (15) versehen ist, die sich von dem betreffenden Teil zu dem anderen Teil hin erstrecken und wobei beide Teile miteinander verbunden werden können, dadurch gekennzeichnet, daß die Vorsprünge (15) Stifte sind, die dazu dienen, das Hülsenteil und das Rahmenteil aneinander zu befestigen und die Einsatzstellung jedes Elementes (17) zu bewirken, indem sie sich durch dieses hindurch zum Eingriff in Löcher des anderen der beiden Teile erstrecken.

2. Prothese nach Anspruch 1, dadurch gekennzeichnet, daß die Stifte (15) an dem Tragrahmenteil (11) ausgebildet sind und sich von diesen nach außen erstrecken, um in Eingriff mit den Löchern (19a) in dem umg b nden Hülsenteil (18) zu kommen.

3. Prothese nach einem der Ansprüche 1 d r 2, dadurch gekennzeichnet, daß das Hülsenteil (18) mit einer Anzahl von integrierten Verlängerungen (20) versehen ist, von denen jede so angeordnet ist, daß sie einer der Stützen (13) des Tragrahmenteils (11) überdeckt.

4. Prothese nach Anspruch 3, dadurch gekennzeichnet, daß jede Tragrahmenstütze (13) mit einem hervorstehenden Zapfen oder mehreren Zapfen (16) versehen ist, auf denen die Klappenelemente (17) befestigt sind.

5. Prothese nach Anspruch 4, dadurch gekennzeichnet, daß jeder hervorstehende Zapfen (10) an der Tragrahmenstütze (13) ausgebildet und mit Mitteln zum Befestigen eines Klappenelementes oder von Klappenelementen (17) daran versehen ist.

6. Prothese nach Anspruch 5, dadurch gekennzeichnet, daß das Befestigungsmittel eine Art Unterlegscheibe oder dergleichen ist, die lösbar auf ihrem zugehörigen Zapfen (16) festklemmbar ist.

7. Prothese nach irgendeinem der Ansprüche 3—6, dadurch gekennzeichnet, daß jede Hülsenverlängerung (20) in sich einen Spalt (21) aufweist, um Mittel zum Zusammenfügen benachbarter Gewebelappen (17) aufzunehmen.

8. Prothese nach irgendeinem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß das Hülsenteil (18) mit einer Anzahl von Einschnitten (22) versehen ist, die in Umfangsrichtung voneinander beabstandet sind und von denen sich jeder teilweise entlang der Länge des Hülsenteiles (18) erstreckt, und die eine Verformung des Hülsenteils (18) zulassen, um ein lösbares, gegenseitiges Ineingriffbringen des Hülsenteiles (18) um das Tragrahmenteil (11) herum zu ermöglichen.

9. Prothese nach irgendeinem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß ein ringförmiger Spannring (30) für eine Anordnung um die Außenfläche der Hülse herum vorgesehen ist, um das Hülsenteil (18) in Eingriff mit dem Tragrahmenteil (11) zu halten.

10. Prothese nach irgendeinem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß das Tragrahmenteil (11) vollständig von einer Gewebeabdeckung (24) umschlossen ist, wodurch die Innenfläche des überdeckten Tragrahmenteils (11) nahtlos ist.

11. Prothese nach Anspruch 10, dadurch gekennzeichnet, daß der Grundkörper (12) des Rahmenteils (11) und das Hülsenteil (18) mit einem ununterbrochenen Gewebestück überdeckt ist.

12. Prothese nach irgendeinem der vorangegangenen Ansprüche, dadurch gekennzeichnet, daß das Hülsenteil (18) vollständig durch eine Gewebeabdeckung (27) umschlossen ist.

13. Prothese nach Anspruch 12, dadurch gekennzeichnet, daß die Gewebeabdeckung (27) einen Ansatz aufweist, der als Nähring (36) ausgebildet ist, welcher sich um die Außenumfangsfläche d r Prozhese h rum erstreckt.

14. Prothese nach Anspruch 4, dadurch gekennzeichnet, daß die integri rten Verlängerungen (20) des Hüls nteils (18) durch einen Verbindungsfaden (23) verkettet sind, um die Möglich-

keit eines Verfangens während des Einsetzens der Prothese zu verringern.

Revendications

1. Prothèse de valve cardiaque comprenant un élément support annulaire (11) pour une pluralité d'éléments de valve en tissu flexible (17), ledit élément support (11) comportant une pluralité de montants espacés (13) qui définissent entre eux des ouvertures pour permettre à une partie de chaque élément de valve (17) de fléchir d'une position ouverte à une position fermée, des moyens pour fixer les éléments de valve à l'élément support comprenant un élément de manchon annulaire (18) concentrique audit élément support (11) et prévu pour bloquer une partie non fléchie de chaque élément de valve (17) en position de fonctionnement entre l'élément support (11) et ledit manchon (18), l'un dudit élément de manchon (18) et dudit élément support (11) comportant une pluralité de saillies (15) s'étendant à partir dudit élément vers ledit autre élément, et cesdits éléments étant prévus pour être fixés l'un à l'autre, caractérisée en ce que les saillies (15) sont des broches qui servent à fixer ensemble l'élément de manchon et l'élément support et à effectuer un positionnement fonctionnel de chaque élément de valve (17) par traversée de celui-ci pour l'accouplement avec des trous prévus dans l'autre desdits éléments de manchon et du support.

2. Prothèse suivant la revendication 1, dans laquelle les broches (15) sont formées sur l'élément support (11) et s'étendent vers l'extérieur, à partir de celui-ci, pour s'engager dans des trous (19a) de l'élément de manchon (18) d'entourage.

3. Prothèse suivant l'une quelconque des revendications 1 ou 2, dans laquelle l'élément de manchon (18) comporte une pluralité de prolongements solidaires (20), dont chacun est prévu pour se superposer à l'un des montants (13) de l'élément support (11).

4. Prothèse suivant la revendication 3, dans laquelle chaque montant (13) du support comporte un ou plusieurs ergots en saillie (16) sur lesquels les éléments de valve (17) sont montés.

5. Prothèse suivant la revendication 4, dans laquelle chaque ergot en saillie (16) est formé sur le montant (13) du support et comporte des moyens pour y fixer un élément ou des éléments de valve (17).

6. Prothèse suivant la revendication 5, dans laquelle les moyens de fixation sont une rondelle ou un élément similaire prévu pour être agrafé de façon libérable sur son ergot associé (16).

7. Prothèse suivant l'une quelconque des revendications 3 à 6, dans laquelle chaque prolongement (20) du manchon comporte une fente (21) qui peut recevoir des moyens pour la jonction de feuillets de tissu adjacents (17).

8. Prothèse suivant l'une quelconque des revendications précédentes, dans laquelle l'élément de manchon (18) comporte une pluralité de fentes (22) espacées circonférentiellement les unes des autres et s'étendant chacune partiellement sur la longueur de l'élément de manchon (18) afin de permettre par déformation de l'élément de manchon (18) un emmanchement libérable de celui-ci autour de l'élément support (11).

9. Prothèse suivant l'une quelconque des revendications précédentes, dans laquelle un anneau de verrouillage annulaire (30) est prévu pour application autour de la surface extérieure du manchon, afin de retenir l'élément de manchon (18) en contact avec l'élément support (11).

10. Prothèse suivant l'une quelconque des revendications précédentes, dans laquelle l'élément support (11) est entièrement entouré par un revêtement (24) de tissu de sorte que la face intérieure de l'élément support recouvert (11) est sans couture.

11. Prothèse suivant la revendication 10, dans laquelle la base (12) de l'élément support (11) et l'élément de manchon (18) sont recouverts d'un élément de tissu continu.

12. Prothèse suivant l'une quelconque des revendications précédentes, dans laquelle l'élément de manchon (18) est entièrement entouré par un revêtement (27) de toile.

13. Prothèse suivant la revendication 12, dans laquelle le revêtement de toile (27) comporte un prolongement formé en un anneau de couture (36) s'étendant autour de la circonférence extérieure de la prothèse.

14. Prothèse suivant la revendication 4, dans laquelle les prolongements (20) solidaires de l'élément de manchon (18) sont reliés par une suture de connexion (23) pour réduire le risque d'accrochage pendant l'insertion de la prothèse.

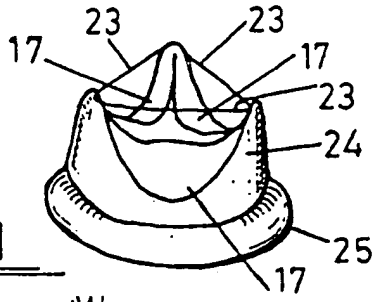

FIG.1

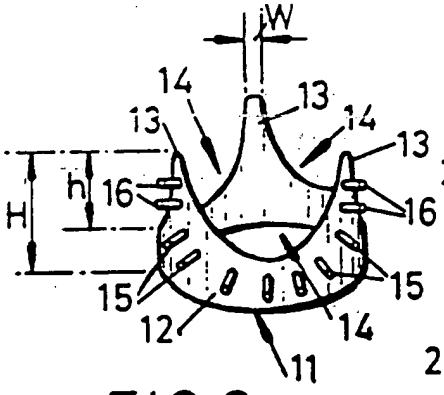

FIG.2

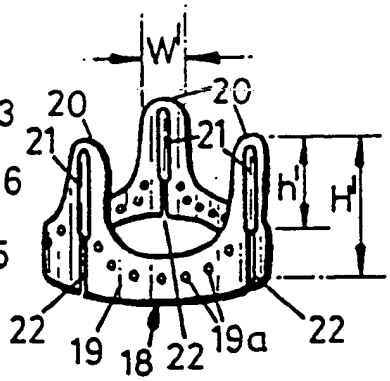

FIG.3

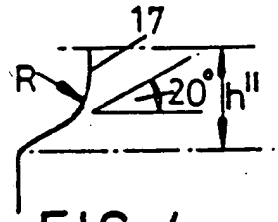

FIG.4a

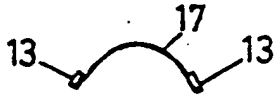

FIG.4b

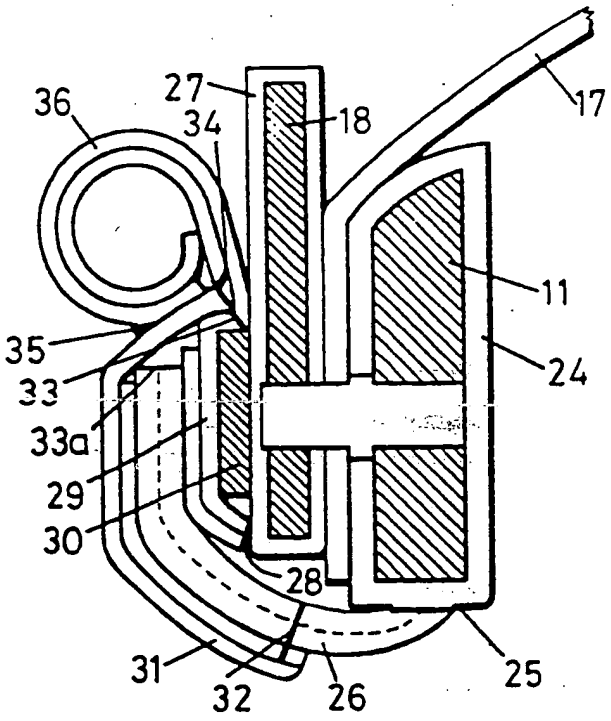

FIG. 5